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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. MYLAN PHARMACEUTICALS INC., Defendant and Counterclaim-Plaintiff.	:	Civil Action No. 3:11-CV-02506-JAP-TJB **REVISED JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

INTRODUCTION

Pursuant to L. Pat. R. 4.3, Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm") (Takeda and Ethypharm together "Plaintiffs") and Defendant Mylan Pharmaceuticals Inc. ("Mylan") provided their Joint Claim Construction And Prehearing Statement on February 9, 2012 (D.I. 59). The parties have since agreed to the construction of the following claim terms: (1) "fine granules" (U.S. Patent No. 6,328,994); (2) "a composition" (U.S. Patent No. 6,328,994); and (3) "A rapidly disintegratable tablet for oral administration and disintegration in the buccal cavity without the use of water" (U.S. Patent No. 5,464,632). To reflect the parties' agreement as to those terms, the parties hereby provide their Revised Joint Claim Construction And Prehearing Statement in advance of the hearing scheduled for August 23, 2012 at 9:30 AM.

I. Construction Of Terms On Which The Parties Agree

1. U.S. Patent No. 6,328,994 ("the '994 patent")

CLAIM TERM	AGREED CONSTRUCTION
Claim 1	
fine granules	fine granules up to and including the enteric coating layer
a composition	composition up to but not including the enteric coating layer
said composition having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole	said composition up to but not including the enteric coating layer having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole
and (ii) an additive	Plain and ordinary meaning; no construction needed.

CLAIM TERM	AGREED CONSTRUCTION
having a hardness strength of about 1 to about 20 kg	Plain and ordinary meaning; no construction needed.
Claim 3	
wherein the fine granules further comprise a basic inorganic salt.	Plain and ordinary meaning; no construction needed.
Claim 4	
wherein the additive comprises a water-soluble sugar alcohol.	Plain and ordinary meaning; no construction needed.
Claim 9	
wherein the basic inorganic salt is a salt of magnesium and/or a salt of calcium.	Plain and ordinary meaning; no construction needed.
Claim 15	
wherein the fine granules are produced by fluidized-bed granulation method.	Plain and ordinary meaning; no construction needed.
Claim 16	
wherein the enteric coating layer comprises an aqueous enteric polymer agent.	Plain and ordinary meaning; no construction needed.
Claim 17	
wherein the aqueous enteric polymer agent is a methacrylate copolymer.	Plain and ordinary meaning; no construction needed.
Claim 18	
wherein the sustained-release agent is a methacrylate copolymer.	Plain and ordinary meaning; no construction needed.
Claim 19	
wherein the sustained-release agent is in an amount of 5-15 weight % relative to 100 weight % of the aqueous enteric polymer agent.	Plain and ordinary meaning; no construction needed.
Claim 21	
wherein the water-soluble sugar alcohol is mannitol.	Plain and ordinary meaning; no construction needed.
Claim 22	
wherein the water-soluble sugar alcohol is in an amount of 5 to 97 weight % relative to 100 weight % of the orally disintegrable tablet apart from the fine granules.	Plain and ordinary meaning; no construction needed.
Claim 23	
wherein the crystalline cellulose is in an amount of 3 to 50 weight % relative to 100 weight % of the tablet apart from the fine granule.	Plain and ordinary meaning; no construction needed.
Claim 26	
which further comprises crospovidone.	Plain and ordinary meaning; no construction needed.
Claim 27	
wherein the oral disintegration time is one minute or less.	Plain and ordinary meaning; no construction needed.

CLAIM TERM	AGREED CONSTRUCTION
Claim 44	
wherein the sustained-release agent is in an amount of 5 to 30 weight % relative to 100 weight % of the aqueous enteric polymer agent.	Plain and ordinary meaning; no construction needed.

2. U.S. Patent No. 5,464,632 ("the '632 patent")

CLAIM TERM, PHRASE, OR CLAUSE	AGREED CONSTRUCTION
Claim 1	
A rapidly disintegratable tablet for oral administration and disintegration in the buccal cavity without the use of water	A tablet that disintegrates rapidly in the mouth without the use of water
wherein said tablet comprises an active substance and	Plain and ordinary meaning; no construction needed.
said active substance being multiparticulate and in the form of coated microcrystals, or coated microgranules	Plain and ordinary meaning; no construction needed.
and wherein said mixture of excipients comprises	Plain and ordinary meaning; no construction needed.
a disintegrating agent	a substance, or mixture of substances, added to a tablet that is a causal agent in its breakup or disintegration after administration
and swelling agent	a substance, or mixture of substances, which, when contacted with liquid, absorbs the liquid and expands in volume
which are responsible for the disintegration of the tablet with the saliva present in the mouth	Plain and ordinary meaning; no construction needed.
to achieve in less than 60 seconds a suspension easy to swallow	Plain and ordinary meaning; no construction needed.
Claim 4	
The tablet of claim 1, wherein the mixture of excipients comprises at least one disintegrating agent selected from the group consisting of carboxymethylcellulose, insoluble reticulated PVP and at least one swelling agent selected from the group consisting of starch, modified starch, and microcrystalline cellulose.	Plain and ordinary meaning; no construction needed.

II. Proposed Constructions Of Disputed Terms

Exhibit A includes (1) each party's proposed construction of each disputed term; (2) an identification of all references from the intrinsic evidence that support that construction, and (3) an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including experts.

III. Identification Of Most Significant Terms For Construction

1. The '994 patent claim terms, the construction of which will be most significant, include:

   a. "An orally disintegrable tablet" (Claim 1)

   b. "fine granules having an average particle diameter of 400 µm or less" (Claim 1)

   c. "an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent" (Claim 1)

   d. "wherein said tablet . . . is orally disintegrable" (Claim 1)

   e. "wherein the average particle diameter of the fine granule is 300 to 400 µm" (Claim 2)

2. The '632 patent claim terms, the construction of which will be most significant, include:

   a. "a mixture of non-effervescent excipients" (Claim 1)

   b. "permits to obtain reduced ph influence in the digestive tract" (Claim 1)

   c. "permits to obtain . . . reduced influence of viscosity" (Claim 1)

IV. Identification of Terms Whose Construction Will Be Case Dispositive or Substantially Conducive to Promoting Settlement

1. The '994 patent claim terms, the construction of which may be dispositive of this action or substantially conducive to promoting settlement, are:

a. "fine granules having an average particle diameter of 400 µm or less" (Claim 1)

b. "an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent" (Claim 1)

c. "wherein the average particle diameter of the fine granule is 300 to 400 µm" (Claim 2)

2. The '632 patent claim terms, the construction of which may be dispositive of this action or substantially conducive to promoting settlement, are:

a. "a mixture of non-effervescent excipients" (Claim 1)

b. "permits to obtain reduced ph influence in the digestive tract" (Claim 1)

c. "permits to obtain . . . reduced influence of viscosity" (Claim 1)

V. Anticipated Length Of Claim Construction Hearing

The parties anticipate that the claim construction hearing will require one day.

VI. Identification Of Claim Construction Witnesses And Testimony

The parties have agreed not to call any witnesses (factual or expert) to offer testimony at the hearing. However, the parties will rely on the declarations and deposition testimony (together with accompanying exhibits) of expert witnesses Dr. Stephen Byrn and Dr. Russell Mumper.

Respectfully submitted,

Dated: August 21, 2012

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EXHIBIT A – Parties' Proposed Constructions and Evidentiary Support for Disputed Claim Terms of U.S. Patent Nos. 6,328,994 and 5,464,632

Parties' Proposed Constructions and Evidentiary Support for USP 6,328,994

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
Claim 1		
An orally disintegrable tablet	**Proposed Construction**: Plain and ordinary meaning. **Evidentiary Support**: 1) Specification: Col. 1, ll. 9-11 Col. 13, ll. 9-15 Col. 17, ll. 57-67 Col. 18, ll. 1-6	**Proposed Construction:** "A tablet that is capable of disintegrating either in the mouth with saliva or in water and then swallowed" **Evidentiary Support:** 1) Specification: Col. 1, ll. 9-11 Col. 13, ll. 9-15 Col. 17, ll. 57-67 Col. 18, ll. 1-6
fine granules having an average particle diameter of 400 µm or less	**Proposed Construction**: fine granules up to and including the enteric coating layer having an average particle diameter of 400 µm (± 10%) or less	**Proposed Construction:** "fine granules having an average particle diameter of 400 µm or less, with a maximum particle diameter of 425 µm or less"

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	Evidentiary Support: Construction taken from *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharms. USA Inc., et al.*, Civil Action No. 10-1723 (D.N.J.) (JAP) (Dkt. 113), dated Oct. 5, 2011 at p. 7. 1) Specification: Claim 1 Abstract Col. 2, ll. 18-21 Col. 5, ll. 43-50, 57-63 Col. 12, ll. 58-59 Col. 19, ll. 32-37 2) Extrinsic Evidence: US Pharmacopeia 429 Snorek, J. of Pharm. Sci., 96:1451-1467 (2007)	**Evidentiary Support:** 1) Specification: Abstract Col. 1, l. 30-39 Col. 1, ll. 44-52 Col. 2, ll. 12-22 Col. 2, ll. 41-49 Col. 3, ll. 14-22 Col. 3, ll. 36-41 Col. 4, ll. 49-62 Col. 5, ll. 43-56 Col. 5, l. 57 – Col. 6, l. 9 Col. 12, ll. 56-65 Col. 13, ll. 52-53 Col. 14, ll. 30-39 Col. 14, ll. 59-60

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		Col. 16, ll. 11-17 Col. 19, ll. 32-37 Col. 20, ll. 25-30 Col. 22, ll. 16-25, 48-50 Col. 24, ll. 11-17 Col. 26, ll. 4-9 Col. 28, ll. 26-31 Col. 30, ll. 38-43 Col. 32, ll. 52-57 Col. 35, ll. 8-14 Col. 36, ll. 34-39 Examples 1-9 2) <u>Prosecution History:</u> Shimizu Declaration dated September 21, 2000, pp. 4-7 EP Patent No. 761,212 (Shimizu) U.S. Patent No. 5,501,861 (Makino)

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent	**Proposed Construction**: The "enteric coating layer" includes a first component that is an "enteric coating agent" which can be a methacrylate copolymer and a second component that is a "sustained-release agent" which can be a methacrylate copolymer. **Evidentiary Support**: 1) Specification: Col 4, ll. 4-16 Col. 5, ll.16-26 Col. 9, ll. 9-35 '994 Patent, claims 17 and 18 '994 Patent, claims 39 and 40 2) Prosecution History: Office Action, dated August 21, 2000 Amendment, dated December 8, 2000 Declaration of Shimizu, dated September 21, 2000 Amendment, dated May 9, 2001	**Proposed Construction:** "an enteric coating layer comprising two discrete, physically separate components, namely a first component which is an enteric coating agent and a second component which is a sustained-release agent, wherein the enteric coating agent controls the location in the digestive system where the active ingredient is released and the sustained release agent releases the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time" **Evidentiary Support:** 1) Specification: Col. 9, ll. 9-35 Col. 20, ll. 30-40 Col. 22, ll. 28-35 Col. 24, ll. 20-28 Col. 25, ll. 50-58 Col. 27, ll. 40-50 Col. 27, ll. 60-68

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	3) Extrinsic Evidence: WO 2006/011159 US 2008/0113030 US 2009/0304789 Vasilevska, K. et al. "Effect of mixtures of soluble Eudragits on release rate of diltiazem hydrochloride from pellets." Pharmazie 46 (Jan. 1991), p. 54. Obeidat, W. et al. "Sustained Release Tablets Containing Soluble Polymethacrylates: Comparison with Tableted Polymethacrylate IPEC Polymers." AAPS PharmSciTech, Vol. 11, No. 1, pp. 54-63, March 2010. Obeidat, W. et al. "Novel Combination of Anionic and Cationic Polymethacrylate Polymers for Sustained Release Tablet Preparation." Drug Dev. and Indus. Pharm., 34:650-660 (2008). Alvarez, D. et al. "Drug-Release Mechanisms. Comparison of Eudragit FS 30D & Eudragit L30 D-55 as Matrix Formers in Sustained-Release Tablets." www.drugdeliverytech-online.com/drugdelivery/200707 (printed 1/9/2012) Holgado, M. et al. "Physical characterization of carteolol: Eudragit L binding interaction." Int'l J. of Pharm. 114 (1995) 13-21.	Col. 29, ll. 60-68 Col. 30, ll. 17-25 Col. 32, ll. 9-16 Col. 32, ll. 30-40 Col. 34, ll. 27-35 Col. 34, ll. 46-55 Col. 36, ll. 42-50 Examples 1-9 2) Prosecution History: Office Action dated August 21, 2000, pp. 2-3 Claim Amendment dated December 18, 2000, pp. 1-3, 6 Office Action dated March 13, 2001, pp. 2-3 Claim Amendment dated May 9, 2001, pp. 2-3, 5-6 Notice of Allowability dated June 1, 200, p. 2 EP Patent No. 761,212 (Shimizu)

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		U.S. Patent No. 5,501,861 (Makino) 3) Extrinsic Evidence: Remington's Pharmaceutical Sciences, pp. 1669-1670; 1676-1677 (18th ed. 1990) Herbert A. Lieberman et al., Pharmaceutical Dosage Forms, Tablets, Vol. 3, Chapter 2, pp. 108-120 (2nd ed. 1990)
enteric coating layer	**Proposed Construction**: The "enteric coating layer" may be constructed by plural (e.g., 2 or 3) layers. **Evidentiary Support**: 1) Specification: Col. 16, ll. 37-38.	**Proposed Construction:** This claim limitation should be considered to have its plain and ordinary meaning, *i.e.*, an admixture of an enteric coating agent and sustained release agent. **Evidentiary Support:** *See* Mylan's Responsive Claim Construction Brief (D.E. 81) at 14-20; Supplemental Declaration of Dr. Russell J. Mumper (D.E. 80-3) at ¶¶ 35-47 and exhibits cited therein.
wherein said tablet . . . is orally disintegrable	**Proposed Construction**: Plain and ordinary meaning **Evidentiary Support**: 1) Specification:	**Proposed Construction:** "wherein said tablet is capable of disintegrating either in the mouth with saliva or in water and then swallowed" **Evidentiary Support:**

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	Col. 1, ll. 9-11 Col. 13, ll. 9-15 Col. 17, ll. 57-67 Col. 18, ll. 1-6	1) Specification: Col. 1, ll. 9-11 Col. 13, ll. 9-15 Col. 17, ll. 57-67 Col. 18, ll. 1-6

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
Claim 2		
wherein the average particle diameter of the fine granule is 300 to 400 µm	**Proposed Construction**: wherein the average particle diameter of the fine granule is 300 to 400 µm (± 10%) **Evidentiary Support**: Construction taken from *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharms. USA Inc., et al.*, Civil Action No. 10-1723 (D.N.J.) (JAP) (Dkt. 113), dated Oct. 5, 2011 at p. 9. 1) Specification: Claims 1 and 2 Abstract Col. 2, ll. 18-21 Col. 5, ll. 43-50, 57-63 Col. 12, ll. 58-59 Col. 19, ll. 32-37 2) Extrinsic Evidence: US Pharmacopeia 429 Snorek, J. of Pharm. Sci., 96:1451-1467 (2007)	**Proposed Construction:** "wherein the average particle diameter of the fine granules is 300 to 400 µm or less, with a maximum particle diameter of 425 µm or less" **Evidentiary Support:** 1) Specification: Abstract Col. 1, l. 30-39 Col. 1, ll. 44-52 Col. 2, ll. 12-22 Col. 2, ll. 41-49 Col. 3, ll. 14-22 Col. 3, ll. 36-41 Col. 4, ll. 49-62 Col. 5, ll. 43-56 Col. 5, l. 57 – Col. 6, l. 9 Col. 12, ll. 56-65

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		Col. 13, ll. 52-53 Col. 14, ll. 30-39 Col. 14, ll. 59-60 Col. 16, ll. 11-17 Col. 19, ll. 32-37 Col. 20, ll. 25-30 Col. 22, ll. 16-25, 48-50 Col. 24, ll. 11-17 Col. 26, ll. 4-9 Col. 28, ll. 26-31 Col. 30, ll. 38-43 Col. 32, ll. 52-57 Col. 35, ll. 8-14 Col. 36, ll. 34-39 Examples 1-9 2) <u>Prosecution History:</u> Shimizu Declaration dated September 21, 2000, pp.

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		2-3, 5-7 EP Patent No. 761,212 (Shimizu) U.S. Patent No. 5,501,861 (Makino)

Parties' Proposed Constructions and Evidentiary Support for USP 5,464,632

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
Claim 1		
a mixture of non-effervescent excipients	**Proposed Construction**: mixture of excipients in which effervescent excipients, if any, are less than 5% by weight of the final composition **Evidentiary Support**: 1) Specification: Col. 2, ll. 40-49 Col. 3, ll. 15-28 2) Prosecution History: Request for Reexamination, dated December 31, 1998	**Proposed Construction:** The absence of effervescent excipients, *i.e.*, "a mixture of excipients incapable of producing a gas in an aqueous environment" **Evidentiary Support:** 1) Specification: Col. 2, ll. 44-49 Col. 3, ll. 15-28 Examples 1-5 2) Prosecution History:

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	USP 3,882,228 USP 4,687,662 WO 91/04757 EP 0 313 328 3) Extrinsic Evidence: Mohrle, R. "Effervescent Tablets." Pharm. Dosage Forms, pp. 285-328, 2nd Ed. 1989 Anderson, N. et al. "Quantitative Evaluation of Pharmaceutical Effervescent Systems I: Design of Testing Apparatus." J. Pharm. Sci., Vol 71, No. 1 (Jan. 1982). Anderson, N. et al. "Quantitative Evaluation of Pharmaceutical Effervescent Systems II: Stability Monitoring by Reactivity and Porosity Measurements." J. Pharm. Sci., Vol. 71, No. 1 (Jan. 1982). Herbert A. Lieberman *et al.*, Pharmaceutical Dosage Forms: Tablets, Vol. 1, Chapter 6, pp. 285, 287-288, 290-291 (2nd ed. 1989)	Request for Re-Examination Dated December 31, 1998 Claim Amendment Dated December 31, 1998 Claim Amendment Dated July 5, 2000 U.S. Patent No. 2,887,437 U.S. Patent No. 3,882,228 U.S. Patent No. 4,016,254 U.S. Patent No. 4,017,598 U.S. Patent No. 4,547,359 U.S. Patent No. 4,666,703 U.S. Patent No. 4,687,662 U.S. Patent No. 4,710,384 U.S. Patent No. 4,867,987 U.S. Patent No. 4,874,614 U.S. Patent No. 4,881,178 U.S. Patent No. 4,886,669 U.S. Patent No. 4,904,477

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		U.S. Patent No. 4,950,484 U.S. Patent No. 5,047,247 U.S. Patent No. 5,069,910 U.S. Patent No. 5,178,878 U.S. Patent No. 5,198,228 U.S. Patent No. 5,409,711 U.S. Patent No. 5,629,016 WO 91/04757 WO 91/16043 EP 003,589 EP 207,041 EP 255,002 EP 273,005 EP 281,200 EP 313,328 EP 347,767

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		EP 408,273 GB 2,067,900 GB 2,086,725 3) Extrinsic Evidence: Herbert A. Lieberman *et al.*, Pharmaceutical Dosage Forms: Tablets, Vol. 1, Chapter 6, pp. 285, 287-288, 290-291 (2nd ed. 1989) Remington's Pharmaceutical Sciences, pp. 1631, 1634 (18th ed. 1990) A study of powder adhesion to metal surfaces during compression of effervescent pharmaceutical tablets. Sendall F.E. *et al.*, J. Pharm. Pharmacol. 1986 Jul; 38(7):489-93. A new multiple-unit oral floating dosage system. I: Preparation and in vitro evaluation of floating and sustained-release characteristics. Ichikawa M. *et al.*, J. Pharm. Sci. 1991 Nov; 80(11):1062-6. Herbert A. Lieberman *et al.*, Pharmaceutical Dosage Forms: Tablets, Vol. 1, Chapter 6, pp. 285, 287-289, 290-291 (2nd ed. 1989) Yamaguchi M. et al., A Disintegration Test for Vaginal Tablets Comparison with BP Test, J. Pharmacol. 1990, 42(11).

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
		Anderson M.P. et al., Lack of Bioequivalence Between Disulfiram Formulations Exemplified by a Tablet/Effervescent Tablet Study, Acta Psychiatr. Scand. Suppl. 1992, 369:31-35. Ash M. and Ash I., ed., Handbook of Pharmaceutical Additives, Grower Publishing Ltd. 1995, pp. 47-50, 770. The Merck Index 12th ed. 1996 pp. 392-393, 1471-1472. FDA database on Dosage Form Definitions, available at http://www.fda.gov/drugs/development/approvalprocess/formssubmissionrequirements/electronicsubmissions/datastandardsmanualmonographs/mcm071666.htm "granule, effervescent" and "tablet, effervescent"
permits to obtain reduced ph influence in the digestive tract	**Proposed Construction**: the active ingredient in the tablet is less influenced by stomach pH (*i.e.*, the drug is coated) **Evidentiary Support**: 1) Specification: Reexamined Patent Claim 1	**Proposed Construction:** This claim limitation is indefinite. **Evidentiary Support:** 1) Specification: Col. 3, ll. 41-51

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	Abstract Col. 1, ll. 6-16 Col. 1, ll. 26-37 Col. 3, ll. 41-51 Col. 7, ll. 9-14 2) Prosecution History: Amendment, dated January 5, 2000	
permits to obtain . . . reduced influence of viscosity	**Proposed Construction**: the formulation influences viscosity less than the prior art formulations of record that have excipients increasing viscosity **Evidentiary Support**: Construction taken from *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharms. USA Inc., et al.*, Civil Action No. 10-1723 (D.N.J.) (JAP) (Dkt. 113), dated Oct. 5, 2011 at p. 13. 1) Specification: Reexamined Patent Claim 1	**Proposed Construction:** This claim limitation is indefinite. **Evidentiary Support:** 1) Specification: Col. 3, ll. 41-51

CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT	DEFENDANT'S PROPOSED CONSTRUCTION AND EVIDENTIARY SUPPORT
	Abstract Col. 3, ll. 41-51 2) Prosecution History Amendment, dated January 5, 2000 Request for Reexamination, dated December 31, 1998 U.S. Patent 4,886,669	

* * *

To the extent permitted, the parties reserve their rights to amend or supplement the constructions and intrinsic and extrinsic evidence set forth herein.